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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,725	02/28/2005	Hitoshi Okamoto	P26510	8296

7055 7590 07/03/2006

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,725	OKAMOTO ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to vectors containing enhancer sequences from the Islet-1 gene, and cells lines containing those vectors.

Group II, claim(s) 9, drawn to transgenic animals comprising vectors comprising enhancer sequences from the Islet-1 gene.

Group III, claim(s) 10-11, drawn to a method of regulating gene expression using Islet-1 gene enhancer sequences into cells.

Group IV, claim(s) 12, drawn to a method for evaluating the differentiation of pluripotent stem cells containing vectors comprising Islet-1 gene enhancer sequences.

Group V, claim(s) 13, drawn to a method for generating motor neurons using vectors comprising Islet-1 gene enhancer sequences.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention lacks novelty. Higashijima et al (Visualization of Cranial Motor Neurons in Live Transgenic Zebrafish Expressing Green Fluorescent Protein Under the Control of the Islet-1 Promoter/Enhancer. Journal of Neuroscience, 2000. (20(1):206-218) listed in applicant IDS filed 6/08/2005 teaches the development of vectors driven by enhancer sequences from the Islet 1-gene promoter (see abstract) for the development of transgenic Zebrafish. Higashijima teaches that segments of a 4.1 kb section of the Islet-1 gene (labeled the ICP region) is responsible for driving expression of the GFP construct in the neurons in the Zebrafish (Figure 1, and page 210, column 1, lines 3-10). Thus Higashijima teaches the claimed invention.

3. The technical feature of Group I is vectors containing enhancer sequences from the Islet-1 gene, and cells lines containing those vectors. The technical feature of Group II is a transgenic animal comprising vectors comprising Islet-1 gene enhancer

sequences. The composition of Group I is different that Group II (the nucleotides plasmid vs. whole animal of the transgenics) and transgenics over-expressing Islet-1 gene enhancer sequences can be produced using alternate vectors from those delineated in Group I. Thus Groups I and II are compositionally, functionally and biologically distinct.

4. The technical feature of Group I is vectors containing enhancer sequences from the Islet-1 gene, and cells lines containing those vectors. The technical feature of Group III is a method of regulating gene expression comprising introducing Islet-1 gene enhancer sequences into cells. The composition of Group I is distinct from the process in Group III. In addition, it is possible to regulate gene expression without the Islet-1 gene enhancer sequences of Group I in cells. The enhancer sequences of Group I could be used in a vector for the generation of a transgenic animal. Thus Groups I and III are compositionally, functionally and biologically distinct.

5. The technical feature of Group I is vectors containing enhancer sequences from the Islet-1 gene, and cells lines containing those vectors. The technical feature of Group IV is a method for evaluating the differentiation of pluripotent stem cells containing vectors comprising Islet-1 gene enhancer sequences. The composition of Group I is distinct from the process in Group IV. In addition, the steps for evaluating the differentiation of stem cells will change if those specific vectors of Group I are not used. Additionally, the enhancer sequences of Group I could be used in a vector for the generation of a transgenic animal. Thus Groups I and IV are compositionally, functionally and biologically distinct.

6. The technical feature of Group I is vectors containing enhancer sequences from the Islet-1 gene, and cells lines containing those vectors. The technical feature of group V is a method for generating motor neurons using vectors comprising Islet-1 gene enhancer sequences. The composition of Group I is distinct from the process in Group V. In addition, it is possible to generate motor neurons without using those vectors in Group I. Additionally, the enhancer sequences of Group I could be used in a vector for the generation of a transgenic animal. Thus Groups I and V are compositionally, functionally and biologically distinct.

7. The technical feature of Group II is a transgenic animal comprising vectors comprising Islet-1 gene enhancer sequences. The technical feature of Group III is a method of regulating gene expression using Islet-1 gene enhancer sequences in cells. The composition of transgenic animals is distinct from the methodology of Group III. The transgenic animals could be used to evaluate systemic changes that result in the over-expression of genes of interest driven by the Islet-1 gene enhancer sequences (blood pressure, hypertension, etc). Thus Groups II and III are compositionally, functionally and biologically distinct.

8. The technical feature of Group II is a transgenic animal comprising vectors comprising Islet-1 gene enhancer sequences. The technical feature of Group IV is a method for evaluating the differentiation of pluripotent stem cells containing vectors comprising Islet-1 gene enhancer sequences. The composition of Group II (transgenic animals) is distinct from the process in Group IV and does not require the use of Group IV in order to do so. Additionally, the transgenic animals could be used to evaluate

systemic changes that result in the over-expression of genes of interest driven by the Islet-1 gene enhancer sequences (blood pressure, hypertension, etc). Thus Groups II and IV are compositionally, functionally and biologically distinct.

9. The technical feature of Group II is a transgenic animal comprising vectors comprising Islet-1 gene enhancer sequences. The technical feature of group V is a method for generating motor neurons using vectors comprising Islet-1 gene enhancer sequences. The composition of Group II (transgenic animals) is distinct from the process in Group V. The transgenic animals could be used to evaluate systemic changes that result in the over-expression of genes of interest driven by the Islet-1 gene enhancer sequences (blood pressure, hypertension, etc). Thus Groups II and V are compositionally, functionally and biologically distinct.

10. The technical feature of Group III is a method of regulating gene expression using Islet-1 gene enhancer sequences in cells. The technical feature of Group IV is a method for evaluating the differentiation of pluripotent stem cells containing vectors comprising Islet-1 gene enhancer sequences. These methodologies are distinct in the steps involved in obtaining results. Group III methods will involve cell-free or cell based transcription, and translation of a plasmid, and thus conditions such as temperature, humidity, media, pH, transfections, etc will be employed. Methodologies for the evaluation for the differentiation will include western analysis of expressed proteins, fluorescent assays on fixed cells, microscopy, etc. Thus these methodologies differ in scope, design, and results. Thus Groups III and IV are compositionally, functionally and biologically distinct.

11. The technical feature of Group III is a method of regulating gene expression using Islet-1 gene enhancer sequences in cells. The technical feature of group V is a method for generating motor neurons using vectors comprising Islet-1 gene enhancer sequences. These methodologies are distinct in the steps involved in obtaining results. Group III methods will involve cell-free or cell based transcription, and translation of a plasmid, and thus conditions such as temperature, humidity, media, pH, transfections, etc will be employed. The methods for generating motor neurons may require whole organism studies, the differentiation of precursor cells, specific environmental conditions/nutrient etc. in order to generate neurons. Thus these methodologies differ in scope, design, and results. Thus Groups III and V are compositionally, functionally and biologically distinct.

12. The technical feature of Group IV is a method for evaluating the differentiation of pluripotent stem cells containing vectors comprising Islet-1 gene enhancer sequences. The technical feature of group V is a method for generating motor neurons using vectors comprising Islet-1 gene enhancer sequences. These methodologies are distinct in the steps involved in obtaining results. The assay for evaluating the differentiation of stem cells into specific cell types will differ tremendously from the method of generating motor neurons. The methodology of Group IV may require northern, western, and southern analysis as well as microscopy etc, where as the method of generating motor neurons include the transfection or transformation of cells lines and the proper culture conditions for those specific protocols. Thus these methodologies differ in scope,

design, and results. Thus Groups IV and V are compositionally, functionally and biologically distinct.

13. Thus Groups I-V are compositionally, biologically, and functionally distinct and capable of supporting individual patents.

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

15. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

16. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on Monday - Friday, 8AM - 4:30 PM.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAM/06/23/06

DAVID GUZO
PRIMARY EXAMINER